(d) a polynucleotide comprising a nucleotide sequence of SEQ ID NO: 6.

REMARKS

1. The title is being amended to even more clearly point out that which Applicant consider to be the claimed invention. As the Examiner will appreciate, the change to the title is fully supported by the specification as originally filed, e.g., please see page 72 lines 26-27; hence, no new matter is being added by the proposed amendment. Applicant appreciates the suggestion for the title as made by the Examiner. Therefore, entry of the amendment hereinabove and reconsideration of the Office Action mailed November 2, 2001 are respectfully requested.

2. The specification is being amended to remove the URL (Uniform Resource Locator) noted at page 22, line 28, and to provide in its place a non-executable name of the same database. The specification is being further amended to provide a "**Brief Description of the Drawings**". Support for this amendment is provided, e.g., at page 70, lines 7-29, in the specification as originally filed; hence, the Examiner will appreciate that no new matter is being added by the proposed amendments. Therefore, entry of the amendment hereinabove and reconsideration of the Office Action mailed November 2, 2001 are respectfully requested.

3. Claims 1-22 are pending in the Application.

4. Claims 6-10 and 22 have been amended without waiver or prejudice.

5. Claims 1-5 are being cancelled without waiver or prejudice, subject to the right to file a continuation application(s) thereto.

6. Claims 13-21 are being canceled without waiver or prejudice, subject to the right to file a divisional application(s) thereto. The Examiner accurately notes Applicant's earlier election of the invention of group 1 (i.e., claims 1-12 and 22), without traverse, during a telephone conversation with Applicant's attorney on August 9, 2001. Hence, claims 13-21 are drawn to a non-elected invention(s) and were withdrawn from further consideration by the Examiner.

7. New claims 23-36 are being added to even more clearly show that which the Applicants consider their invention. Support for this amendment is provided, e.g., at page 75, lines 6-27 in the specification and in the claims as originally filed; hence, the Examiner will appreciate that no new matter is being added by the proposed amendments. Therefore, entry of the amendments hereinabove and reconsideration of the Office Action mailed November 2, 2001 are respectfully requested.

10. After entry of the amendments hereinabove, Claims 6-12 and 22-36 remain pending in the application.

11. Claim 22 was objected to as depending from two different claims. Applicants have amended Claim 22 to rewrite it as a proper independent claim. The objection to dependent claims 11-12 would thus be mooted as a result of the amendment to claim 10. The Examiner will appreciate that no new matter is being added by the proposed amendment. Therefore, entry of the amendment hereinabove and reconsideration of the Office Action mailed October 29, 2001 are respectfully requested.

12. Claims 1-12 and 22 were rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The basis of the rejection under 35 USC §101 as noted by the Examiner was that the claimed poly nucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. A number of other arguments were

also made by the Examiner to provide a basis for the asserted utility rejection Applicant respectfully traverses this rejection.

Applicant appreciates the careful review of the specification by the Examiner. Applicant, however, disagrees and rebuts the conclusions drawn by the Examiner on the utility of Applicant's teachings.

A claimed invention need only meet one of its stated objectives to comply with the Section 101 utility requirement.

Applicant's specification teaches for example the use of hybridization techniques and probes complementary to PFI-002. The specification teaches at page 25, line 23 to page 29, line 13 the use of hybridization techniques and at page 63, line 21 to page 64, line 32 the use of probes in order to assess the claimed nucleic acid sequences. Reference is also made to the Examples, which teach, selected sequences that may be utilized in performing such methods. These techniques can be practiced by one of skill in the art without undue experimentation. Screening test samples for a DNA target would indeed be a real world and practical use of the claimed sequences.

Further, at page 54, line 36 to page 56, line 6 of the specification Applicant teaches the use of immunological methods to assess the claimed polypeptide sequences. Again, such methods can be practiced by one of skill in the art without undue experimentation. Screening test samples for a polypeptide target would be a real world and practical use of the claimed polypeptide sequences. As an example, the use of such immunological methods is provided for in the papers of Behr et al., Q J Nucl Med v 43 pp268-280 (1999) and Eckard et al., Curr Med Chem v7 pp897-910 (2000) both enclosed with the Supplemental Information Disclosure Statement, submitted on even date herewith. As noted, monoclonal antibodies could be used for such immunochemical methods. The production of monoclonal antibodies is conventional for one of skill in the art. See Hybritech v. Monoclonal Antibodies 281 USPQ 81,94 (Fed.Cir. 1986)

In further responding to the Section 101 rejection, Applicants draw the Examiner's attention to the Utility Guidelines made effective on January 5, 2001 (66 Fed Reg. 1092 (2001)). Applicant submits that the claims of the present invention are directed in part to nucleic acid sequences, which encode polypeptides, and protein sequences belonging to the

class of proteins known as G-protein coupled receptors. This finding is supported by homology analyses of the claimed sequences to existing nucleic acids or polypeptides having an accepted utility. Data supportive of this position is found in the Examples.

The identification of the above references as noted in the Supplemental Information Disclosure Statement should not to be construed as an admission of Applicants or attorneys for Applicants that the references are available as prior art against the pending claims.

In view of the foregoing, Applicant respectfully requests reconsideration of the Office Action mailed November 2, 2001.

12. Claims 1-12 and 22 were also rejected under 35 U.S.C. §112, first paragraph as not being supported by either a specific and substantial asserted utility or a well-established utility for reasons stated in the rejection under 35 U.S.C. § 101, one skilled in the art would not know how to use the claimed invention. Applicant respectfully traverses this rejection.

The questions of whether a specification provides an enabling disclosure under Section 112, first paragraph and whether an application satisfies the utility requirements of Section 101 are closely related and should be similarly resolved. See In re Schwartz 56 USPQ2d 1703, 1703 (Fed. Cir. 2000).

Applicant submits that for reasons stated above in rebutting the prima facie rejection based on lack of utility under Section 101 that the corresponding rejection imposed under Section 112, first paragraph should be withdrawn. One skilled in the art could readily practice the claimed invention based on the teachings provided in the specification. Applicant therefore respectfully request reconsideration of the Office Action mailed November 2, 2001.

14. Claims 1-12 and 22 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, on the basis of containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the art, at the time the application was filed had possession of the claimed invention. In addition, the Examiner

argued that the specification fails to describe polynucleotides having identity of 70% to 95% to SEQ ID NO: 1, which are encompassed by the claims. Applicant respectfully traverses this rejection.

First, Applicants acknowledge the statement of the Examiner that the specification supports possession of a nucleic acid molecule of SEQ ID NO: 1 encoding the polypeptide of SEQ ID NO: 2 at page 11 of the Office Action.

Applicant, however, disagrees with the Examiner that the specification is not enabled for the breath of the claims for nucleic acid and amino acid sequences and to the described G-coupled protein receptor.

Applicant submits that the undue experimentation test, as part of the enablement requirement of 35 U.S.C. § 112, first paragraph, involves a balancing of the results of a factual inquiry when utilizing the Wands factors (In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988)) as they apply to the circumstances of a particular case. Applicants note that Wands provides at 1404 that "[A] considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In addition the Federal Circuit has noted that it is not mandatory for a court to review all of the Wands factors to find a specification enabling. "They are illustrative not mandatory." See Amgen v. Chugai Pharmaceutical 18 USPQ2d 1016,1027(Fed. Cir. 1991).

Applicant's specification provides the necessary guidance and direction to those of ordinary skill in the art to practice the presently claimed invention, and therefore properly meets the enablement requirements of 35 U.S.C. § 112, first paragraph. Applicant draws the Examiner's attention to the Examples provided in the specification at page 71 line 1 to page 77 line 5 where Applicant provides teaching to those of ordinary skill in the art to perform sequence analysis, cloning and expression of resultant proteins and tissue distribution studies. Further supportive teachings are also provided in the specification.

Responding to the Examiner's concern for the percentage of identity for nucleic acid sequences Applicants note the paper of Lewis entitled "PROBFIND: A Computer Program For Searching Probes For Peptide Sequences," NAR 14, 567-570 (1986). The

paper of Lewis provides support to Applicant's position that one of ordinary skill in the art would be able to use such available tools in the selection or determination of identity of nucleic acid sequences. The paper of Lewis is provided as part of the Supplemental Information Statement filed herewith.

The Examiner will appreciate that in the practice of the claimed invention some variability will occur in the methodologies, when in the hands of those skilled in the art. Applicant submits that for all practical purposes that the Examiner would seem to require Applicant to limit the claims to specific sequences disclosed in the specification. To demand that the first to disclose should limit his claims to only what he has found will work would not serve the constitutional purpose of promoting progress in the useful arts. See In re Goffe, 191 USPQ 429, 431 (CCPA 1976).

Applicant's claims recite nucleic acid and amino acid sequences. Sequence information as such, would clearly allow one of ordinary skill in the relevant art to reasonably conclude that the inventor had possession of the claimed invention. See Vas-Cath v. Mahurkar 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The Federal Circuit has also stated in Fiers v. Revel 25 USPQ2d 1601, 1607 (Fed. Cir. 1995) that an adequate written description of a DNA sequence is provided by "a precise definition, such as by structure, formula, chemical name or physical properties".

In further support of Applicant's position, Applicants draw the Examiner's attention to Comment 9 of the Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, 1,"Written Description" Requirement at Fed. Reg. v.66 (4) p. 1099, 1101 (January 5, 2001). Comment 9 concludes by stating that "[T] here is no basis for a per se rule requiring disclosure of a complete DNA sequence or limiting DNA claims to only the sequence disclosed." Applicant respectfully submits that for the reasons discussed, the specification would enable a person of ordinary skill in the art to practice the claimed invention without undue experimentation. Therefore, reconsideration of the Office Action mailed November 2, 2001 is respectfully requested.

15. Claims 1, 8 and 22 were rejected under 35 U.S.C. §112, second paragraph

as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

Applicant appreciates the useful suggestions made by the Examiner in order to moot the stated rejections to the specified claims. Claim 1 has been cancelled and rewritten as claim 23 to make moot the stated rejection. Claims 8 and 22 have been amended to make moot the stated rejection specific to each of the claims. The newly added claims have been written to incorporate the useful suggestions made by the Examiner. As the Examiner will appreciate, no new matter is being added by the proposed amendments. Therefore, entry of the amendments hereinabove and reconsideration of the Office Action mailed November 2, 2001 are respectfully requested.

15. Claims 1-10 and 22 were rejected under 35 U.S.C. §102(b), as being anticipated by Database EMBL Accession No. AS008571 (August 3, 1999). Applicant respectfully traverses this rejection.

Applicant submits that the Examiner has not established a prima facie case of anticipation rejection based on the teaching of the EMBL reference. The EMBL sequence listing is drawn to a genomic sequence of 216kb. The disclosure accompanying the sequence notes that the sequence was "replaced" on May 5, 200 and is a 'working draft' sequence of 9 unordered pieces. Such statements raise a question as to what is the teaching that the reference actually provides and further whether it is enabling. There is, simply no teaching in the EMBL reference of how one of skill in the art would select a specific region of the EMBL sequence to anticipate Applicant's claimed invention without further analyses. Nor is it clear that one of skill in the art without reference to Applicant's disclosure would even recognize that a portion of the EMBL sequence, consisting of less than one percent of the entire EMBL sequence, could be utilized to anticipate Applicant's claimed invention with some expectation of success. Therefore, reconsideration of the Office Action mailed November 2, 2001 is respectfully requested.

16. Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Lubert Stryer (Biochemistry, 3rd Edition, pp71-90, W. H. Freeeman, 1988, on the basis that the claim recites "a polynucleotide fragment" of the polynucleotide of SEQ ID NO: 1 or its complement. Applicant respectfully traverses this rejection.

Applicant has noted the Examiner's concern with regard to the stated objection and has complied to make moot the basis of the rejection in the amended and new claims submitted herewith. Therefore, reconsideration of the Office Action mailed November 2, 2001 is respectfully requested.

16. Claims 1, 7-12 and 22 were rejected under 35 U.S.C. 102(b) as being Anticipated by Tan, et al., on the basis that Tan et al. disclose a nucleotide sequence of a human G-protein-coupled receptor (FM3) with two regions that contain 19 and 26 contiguous nucleotides identical to that set forth in SEQ ID NO: 1. Additional grounds were also noted by the Examiner to support the rejection based on the Tan et al. reference. Applicant respectfully traverses the rejection.

Applicant submits that the Examiner has not established a prima facie case of anticipation rejection based on the teaching of the Tan et al. reference. While the Tan et al reference concerns a particular subtype of a neuromedin U receptor the divergence of the specified sequence taught by Tan et al. to that taught by the Applicant does not meet the requirements of a prima facie anticipation rejection. There is simply no further teaching in the Tan el al. reference to meet that provided in Applicant's claims or any basis for selecting only the region of the Tan et al. sequence noted by the Examiner for purposes of further analysis. Therefore, reconsideration of the Office Action mailed November 2, 2001 is respectfully requested.

18. Claim 12 was rejected under 35 U.S. C. 102(b) as being anticipated by Maniatis et al. (Molecular Cloning: A Laboratory Manual, 2nd Edition, Book 3, pp17.37-17.41, Cold Springs Harbor Laboratory Press, 1989), on the basis that Maniatis et al. teach membrane preparation of a cell by centrifugation and thus the reference meets the limitations of Claim 12. Applicant respectfully traverses this rejection.

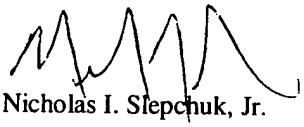
Applicant submits that the Examiner has not established a prima facie case of anticipation rejection based on the teaching of the Maniatis et al. reference. Claim 12 is a dependent claim incorporating the subject matter of Claim 1, now rewritten as Claim 23. Consequently, the Maniatis et al reference does not properly anticipate the subject matter of Claim 12. Therefore, reconsideration of the Office Action mailed November 2, 2001 is respectfully requested.

19. Attached hereto is a marked-up version of the changes made to the title, specification, figures and claims by the current amendment. The attached page is captioned "**MARKED VERSION TO SHOW AMENDMENTS**."

20. Applicants believe that the amendments hereinabove to the claims place the Application in condition for allowance. Therefore, entry of the amendments hereinabove and reconsideration of the Office Action mailed November 2, 2001 are respectfully requested. Such prompt and favorable action is earnestly solicited.

Date: April 26, 2002

Respectfully submitted,



Nicholas I. Stepchuk, Jr.
Attorney For Applicants
Reg. No. 32,174

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 715-0081

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Honorable Commissioner of Patents, Washington, D.C. 20231 on this 26'th day of April, 2002.

By: Janice Denison

COPY OF PAPERS
ORIGINALLY FILED

MARKED VERSION TO SHOW AMENDMENTS

IN THE TITLE

Please amend the title to read as follows:

-- [NOVEL POLYPEPTIDE] A Subtype of Neuromedin U Receptor --.

IN THE SPECIFICATION

At page 23, lines 5-15, please rewrite the paragraph as follows:

--As indicated, for some applications, sequence homology (or identity) may be determined using any suitable homology algorithm, using for example default parameters. For a discussion of basic issues in similarity searching of sequence databases, see Altschul et al. (1994) Nature Genetics 6:119-129. For some applications, the BLAST algorithm is employed, with parameters set to default values. The BLAST algorithm is described in detail at

[http://www.ncbi.nih.gov/BLAST/blast_help.html] the NCBI database. Advantageously, "substantial homology", when assessed by BLAST, equates to sequences which match with an EXCEPT value of at least e-7, preferably about e-9 and most preferably e-10 or lower. The defaulted threshold for EXCEPT in BLAST searching is usually 10. --.

IN THE CLAIMS

Please amend claims 6-10 as follows:

6. (Amended). The polynucleotide of claim [1] 23, comprising a nucleotide sequence that has at least 95% identity to the polynucleotide of (a) or (b).

7. (Amended). The polynucleotide of claim [1] 23, wherein said polynucleotide encodes a G-protein coupled receptor (GCPR).

8. (Amended). The polynucleotide of claim [1] 23, wherein said polynucleotide is a probe or primer comprising at least 15 contiguous nucleotides.

9. (Amended). A vector comprising a polynucleotide of claim [1] 23.

10. (Amended). A host cell transformed or transfected with the vector of claim 9, wherein said host cell expresses the polynucleotide of SEQ ID NO: 1 under conditions sufficient for expression of the polynucleotide.

Please amend claim 22 as follows:

22. (Amended) [An] A [animal] host cell genetically modified to increase expression of a DNA sequence encoding a [polypeptide] protein of [claim 13 and/or comprising a functionally disrupted endogenous gene encoding a polypeptide of claim 13] SEQ ID NO: 2.